REMARKS

Claims 24 and 31-32 were pending in the subject application. Applicants have herein amended claims 24 and 31-32 and added new claims 33-54. Claims 24 and 31-54 are now pending in the subject application.

Claim 24 has been amended to specify that the recited compounds also encompass hydrates or solvates of the compounds. Support for the amendment to claim 24 can be found in the original specification at for example, original claim 24.

Claims 31 and 32 have been amended to depend from new claim 33.

New claims 33-54 are directed to a genus of a compound of formula 1. Support for new claims 33-54 can be found in the original specification at, for example, original claims 1-7 and 9-23, respectively; page 13, lines 19-20; page 18, lines 13-14; page 19, lines 20-21; page 24, lines 12-16 and 19-20; Example 8, pages 57-58; and Example 99, pages 117-119.

No new matter is added by these amendments and Applicants respectfully request their entry.

I. Amendment to Claim 24

In a Notice of Allowance and Fee(s) Due mailed on September 29, 2006, the Examiner found claims 24 and 31-32 allowable. Claim 24 has now been amended to recite the hydrates and solvates of the recited compounds.

Original claim 24 recited hydrates and solvates of the claimed compounds. In an Office Action mailed on December 7, 2005 the Examiner rejected original claim 24 under 35 U.S.C. § 112, first paragraph. The Examiner stated that that "[t]he claim[s] contain subject matter that was not described in the specification in such a way as to enable any person skilled in the art to which it pertains, or with which it is most closely connected, to made and use the invention in commensurate in scope with these claims." In particular, the Examiner asserted that "the specification, while being enabling for making pharmaceutically acceptable salts does not reasonably provide enablement for making solvate or hydrate." The Examiner contended that "there should be showing to support that solvates and hydrates of these compounds exist and therefore can be made." The Examiner also asserted that it is not predictable "whether solvates will form or what their composition will be." The Examiner supported his argument by application of the Wands' factors and rejected the terms "solvates" and "hydrates" on the grounds that the

Applicants' disclosure was not sufficient to enable one of ordinary skill in the art to practice the invention as to "solvate" and "hydrate.' The Examiner asserted that the primary factors leading to a conclusion of lack of enablement stems from the undue experimentation required to practice the invention in light of the absence of working examples, the lack of predictability in the art, and the broad scope of the claims.

In an Amendment filed on April 4, 2006, Applicants stated their disagreement with the Examiner's assertion that the specification did not reasonably provide enablement for making solvates or hydrates. However, in order to advance the prosecution of this application, Applicants amended 24 to delete the terms "solvates" and "hydrates." Applicants have reconsidered this earlier rejection of claim 24 and believe that the subject specification does reasonably provide enablement for making solvates or hydrates of the claimed compounds for the reasons set forth below.

Applicants note that the Examiner's position was based on an improper standard. First, the Examiner looked to predictability in terms of whether or not a particular species of solvate or hydrate can occur. Applicants submit that this is an improper argument. The issue is not whether a solvent or solvate or hydrate occurs, but given that the compounds of the invention are prepared, would one of skill in the art be able to identify that compound as a solvate or hydrate without undue experimentation. Applicants submit that it is routine practice within the pharmaceutical industry to characterize compounds in terms of hydrates and solvates.

In addition, the Examiner's the Examiner's analysis did not consider all the evidence related to each of the Wands' factors, which require that any conclusion of nonenablement must be based on the evidence as a whole. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). For example, the Examiner alleged that Applicants' disclosure is not sufficient to enable one of ordinary skill in the art to practice "solvate" and "hydrate" because the "numerous examples presented all failed to produce a solvate." Applicants respectfully traverse the Examiner's rejection. Compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed; "representative [samples] are not required by the statute and are not an end in themselves." *In re Robins*, 429 F.2d 452, 457 (CCPA 1970). Furthermore, the law does not require that everything necessary to practice the invention be disclosed. In fact the Federal Circuit has advised that what is well known is best omitted. *In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991). All that is necessary is that one skilled in the art be able

to practice the claimed invention, given the level of knowledge and skill in the art.

One skilled in the art of synthetic organic chemistry would readily know that solvates and hydrates result from routine synthesis of compounds. Consider, for example, the procedure of isolation of a target molecule. This technique is so fundamental and routine in the synthesis of compounds that it is one of the first laboratory skills acquired in a basic college organic chemistry class. One skilled in the art of synthetic organic chemistry knows that there will always be residual solvent in the final product. Furthermore, a bench level chemist maybe satisfied with isolating the final product as a roto-evaporated foam, oil, or glass. Crystallization to yield analytical grade "C, H, N" quality material is not the standard of purity for which production of a compound is deemed to have occurred. Applicants are left to wonder whether the Examiner, who by his arguments seems so well versed in synthetic organic chemistry, really is postulating that isolation of a product as a foam from a roto-evaporated solution of ethyl acetate would not produce an ethyl acetate solvate of the desired product. Would the result differ with any solvent chosen? Even assuming *arguendo* a chemist did not appreciate this fact, analysis of the isolated compound would demonstrate the presence of solvent, the content of which could be readily determined by gas chromatography or in NMR spectra. Applicants note that the United States Pharmacopeia (USP), the official public standards-setting authority for all prescription and over-the-counter medicines, dietary supplements, and other healthcare products manufactured and sold in the United States, has set industry standards that allow for the inclusion of such impurities in the compounds! Because residual solvent is expected industry-wide, no undue experimentation would be required to practice the present invention as all the methods needed to practice the invention are well known.

The Examiner alleged that it is not predictable whether solvates will form or what their composition will be. The Examiner cited West (Solid State Chemistry) for the proposition that predicting the formation of solvates or hydrates of a compound and the number of molecules of water or solvent incorporated into the crystal lattice of a compound is complex and difficult. Applicants appreciate the Examiner's citation but are at a loss to understand what "predicting" a specific "crystal lattice" structure has to do with the present invention. Contrary to the Examiner's position, West accepts the existence of solvates and hydrates. As described above, solvates and hydrates refer to isolated compounds containing residual solvent. Because it is well known in the art that

solvates and hydrates routinely result from synthetic processes, one skilled in the art could readily anticipate the existence of solvates and hydrates of the compounds of formula 1, and thus, there is predictability in the art. Because there is predictability in the art, the amount of guidance or direction needed to teach how to make or use the solvates and hydrates is minimal, and Applicants have provided a fully enabling disclosure.

"The artisan's knowledge of the prior art and routine experimentation can…fill the gaps, interpolate between embodiments, and…extrapolate beyond the disclosed embodiments…" *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244 (Fed. Cir. 2003). The scope of enablement must only bear a "reasonable correlation" to the scope of the claims. *In re Fischer*, 427 F.2d 833, 839 (CCPA 1970).

Solvates and hydrates of the compounds of the invention are routinely made in preparation of the compounds of the invention. The record is clear and thus the public will have notice as to Applicants' scope of protection when the patent issues.

Based on the foregoing, Applicants respectfully request that the Examiner reconsider his rejection to the terms solvates and hydrates and allow the claim as amended to issue.

II. New Claims 33-54

New claims 33-54 are directed to a directed to a genus of a compound of formula 1, or a pharmaceutically acceptable salt, solvate, or hydrate thereof. As noted above, new claims 33-54 are based on original claims 1-7 and 9-23.

In an Office Action mailed on December 7, 2005 the Examiner rejected original claims 1-7 and 9-23 under 35 U.S.C. § 112, paragraph, first paragraph as allegedly being non-enabling for making solvates or hydrates for the reasons discussed above with regard to claim 24.

The Examiner also rejected original claims 1-7 and 9-23 under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent Application Publication No. 2003/0171359 to Dahmann et al. ("Dahmann"); and rejected original claims 1-9 and 11-23 under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent Application Publication Nos. 2005/0009853 to Bornemann et al. ("Bornemann") and International Publication No. WO 03/030909 to Nagarathnam et al. ("Nagarthanam") for the reasons set forth in the office action of December 7, 2005.

In addition, the Examiner rejected claims 1-23 under 35 U.S.C. § 103(a) as allegedly being obvious over Dahmann, Bornemann or Nagarathnam for the reasons set forth in the office action December 7, 2005.

In an Amendment filed on April 4, 2006 Applicants amended certain of the original claims 1-7 and 9-23 claims and argued against the 35 U.S.C. §§ 102 and 103 rejections, noting that none of the cited references disclosed or suggested the compounds recited in the amended claims. In addition, Applicants stated their disagreement with the Examiner's 35 U.S.C. § 112, first paragraph rejection; however in order to advance the prosecution of this application, Applicants amended claims 1-7 and 9-23 to delete the terms "solvates" and "hydrates."

In an Office Action mailed on June 28, 2006 the Examiner withdrew his 102(e) rejections based on Dahmann and Bornemann, but maintained his 102(e) rejection of claims 1-9 and 11-23 as allegedly being anticipated by Nagarathnam. However, the Examiner maintained his 103(a) rejections of claims 1-23 as allegedly being obvious over Dahmann, Bornemann or Nagarathnam.

In an Amendment filed on August 24, 2006, Applicants canceled claims 1-7 and 9-23 in order to expedite the allowance of this case.

Applicants have reconsidered the earlier rejection of these claims, and believe that new claims 33-54 are patentable over the art of record, because none of Dahmann, Bornemann or Nagarathnam disclose, teach or even suggest any compound of formula I wherein R^4 is selected from the group consisting of C_6-C_{10} aryl and 5-10 membered heteroaryl, and wherein said aryl and heteroaryl moieties of the foregoing groups are each substituted by 1 to 3 substituents independently selected from the group consisting of SR^6, SOR^6, SO_2R^6, SO_2NH_2, SO_2NHR^6, $SO_2NR^6R^7$, $NHSO_2R^6$ and $NR^6SO_2R^6$.

Applicants further submit that that new claims 33-54 as to the salts and hydrates of the recited compounds for the same reasons as discussed above with regard to claim 24.

CONCLUSION

No additional fee is believed due in connection with this amendment. However, if any fee is due, the Examiner is authorized to charge the fee to Applicants' Deposit Account No. 16-1445.

If the Examiner wishes to comment or discuss any aspect of this application or response, Applicants' undersigned attorney invites the Examiner to call him at the telephone number provided below.

Respectfully submitted,

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